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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte JON A. WOLFF and VLADIMIR G. BUDKER

Appeal 2008-2708
Application 09/707,000
Technology Center 1600

Decided: December 18, 2008

Before TONI R. SCHEINER, DONALD E. ADAMS, and LORA M. GREEN, *Administrative Patent Judges*.

GREEN, *Administrative Patent Judge.*

DECISION ON APPEAL

This is a decision on appeal[1] under 35 U.S.C. § 134 from the Examiner's final rejection of claims 1-3, 6-9, 11-14, 16-22, 24-26, 28-31, 34-36, and 39. We have jurisdiction under 35 U.S.C. § 6(b).

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[1] This Appeal is related to Appeal No. 2007-2711, decided January 16, 2008.

STATEMENT OF THE CASE

The claims are directed to an *in vivo* process for delivering skeletal muscle cells in a limb of a mammal. Claims 1and 39 are representative of the claims on appeal, and read as follows:

1. An *in vivo* process for delivering polynucleotides to skeletal muscle cells in a limb of a mammal, comprising:

a) inserting an injector selected from the group consisting of a syringe needle and catheter into an artery in said limb;

b) applying a device for impeding blood flow to the surface of the skin of said limb;

c) applying sufficient pressure against said limb with said device to occlude blood flow to said limb; and

d) injecting a solution containing the polynucleotides through said injector into the lumen of said artery distal to the occlusion thereby delivering the polynucleotides to said skeletal muscle cells distal to said occlusion in the limb.

39. An *in vivo* process for delivering polynucleotides to skeletal muscle cells in a limb of a mammal, comprising:

a) inserting an injector selected from the group consisting of a syringe needle and catheter into a blood vessel in said limb in the mammal and applying pressure to the blood vessel wherein the pressure occludes blood flow through said blood vessel and is applied to the skin of said limb by a device external to the skin of said mammal and;

b) injecting a solution containing the polynucleotides into the lumen of said blood vessel distal to the occlusion thereby delivering the polynucleotides to said skeletal muscle cells in the limb distal to the occlusion; and

c) wherein function of the limb is not affected by inserting the injector, applying pressure to the vessel, and injecting the solution.

We affirm.

ISSUE[2] (Indefiniteness)

The Examiner concludes that claims 1 and 39 are unclear and do not distinctly and clearly set forth the metes and bounds of the claimed invention.

Appellants contend that the meaning of the objected to limitations are clear when read in light of the Specification.

Thus, the issue on Appeal is: Are the meanings of the limitations objected to by the Examiner clear when read in light of the Specification?

FINDINGS OF FACT

FF1 The Examiner rejects claims 1-3, 6-9, 11-14, 16-22, 24-26, 28-31, 34-36, and 39 under 35 U.S.C. § 112, second paragraph, for failing to particularly point out and distinctly claim the subject matter that Appellants regard as the invention (Ans.[3] 16).

FF2 The Examiner concludes step b) of claim 1 is indefinite in the recitation of "'applying a devise for impeding blood flow to the surface of the skin.'" (*Id.* at 17.) According to the Examiner, "[i]t is unclear if applicants are attempting to limit where the blood flow has been impeded (to the surface of the skin) or if applicants are attempting to limit where the device is applied (to the surface of the skin)." (*Id.*)

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[2] We note that the Examiner has presented numerous claim objections, but acknowledges that the claim objections are not for review on Appeal (Ans. 7).

[3] All references to the Answer are to the Examiner's Answer dated November 29, 2007.

FF3 The Examiner also concludes that step c) of claim 1 is also indefinite (*id.*). Specifically, the Examiner finds that the "metes and bounds of 'sufficient pressure' required 'to occlude blood flow to said limb' in claim 1, step c) is unclear," as the "[S]pecification and the art at the time of filing do not define the amount of pressure required to occlude blood flow as claimed." (*Id.*)

FF4 The Examiner further concludes that step d) of claim 1 is indefinite, as "'said occlusion'" lacks antecedent basis (*id.*). According to the Examiner, "[l]iteral antecedence is required when using the term 'said,'" thus "'to occlude blood flow' in step c) is inadequate antecedent basis for the phrase." (*Id.*)

FF5 Claim 39 is indefinite, the Examiner concludes, "because it does not recite all the steps of the method; mere delivery of polynucleotides to cells does not have a disclosed use." (*Id.*)

FF6 Finally, the Examiner concludes that step c) of claim 39 is indefinite, "because the phrase 'wherein function of the limb is not affected by inserting the injector, applying pressure to the vessel, and injecting the solution' is written as an active step (e.g. performing an action, e.g. inserting, injecting, etc.) but is actually a functional limitation of the overall method.'" (*Id.* at 18.)

PRINCIPLES OF LAW

"The test for definiteness is whether one skilled in the art would understand the bounds of the claim when read in light of the specification." *Miles Laboratories, Inc. v. Shandon, Inc.*, 997 F.2d 870, 875 (Fed. Cir.

1993). Claims are in compliance with 35 U.S.C. § 112, second paragraph, if "the claims, read in light of the specification, reasonably apprise those skilled in the art both of the utilization and scope of the invention, and if the language is as precise as the subject matter permits." *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1385 (Fed. Cir. 1986).

ANALYSIS

As to the Examiner's conclusion in FF2, Appellants argue that the "Examiner has taken the phrase out of context," and is thus misinterpreting it (App. Br.[4] 10). We agree.

The Specification states:

> The term cuff means a device for impeding blood flow through mammalian internal blood vessels. However, for purposes of the claims, cuff refers specifically to a device applied exterior to the mammal's skin and touches the skin in a non-invasive manner. In a preferred embodiment, the cuff is a device that applies external pressure to the mammalian skin and thereby pressure is applied internally to the blood vessel walls.

(Spec. 5.)

Thus, it is clear that the phrase "applying a device for impeding blood flow to the surface of the skin," when read in light of the Specification, requires that the device be applied to the surface of the skin.

As to the Examiner's conclusion in FF3, Appellants argue that the Specification teaches the use of sphygmomanometers and tourniquets, are widely used (App. Br. 10). Appellants further assert:

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[4] All references to the Appeal Brief are to the Appeal Brief dated September 20, 2007.

> It is well known that an individual's blood pressure varies from person to person. It follows that variable applications of pressure would be required to occlude blood flow in different people. People trained in measuring blood pressure can easily determine when blood flow has been occluded in any individual simply by listening through a stethoscope. Simple mechanical/electrical devices that can also detect occlusion of blood flow in a particular individual have been commercially available for many years. On page 5, lines 17-19, the Specification states: "The vessel walls are forced to constrict in an area underneath the cuff in amount sufficient to impede blood from flowing at a normal rate." Since the amount of pressure required to occlude blood flow varies from person to person, and the amount of pressure required to accomplish such occlusion is easily determined, Applicants believe that the terminology "sufficient pressure" is clear and does not require further definition.

(*Id.* at 11.)

We agree with Appellants arguments, and conclude that the skilled artisan would understand the metes and bounds of "applying sufficient pressure against said limb with said device to occlude blood flow to said limb."

As to the Examiner's conclusion in FF4, Appellants argue that the recitation of "'to occlude blood flow'" in step c) of claim 1 is sufficient antecedent basis, as if blood is occluded, an occlusion is formed (App. Br. 11).

We agree that the skilled artisan would understand that the recitation of "said occlusion" in step d) of claim 1 refers to the occlusion formed by occluding the blood flow in step c) of claim 1.

As to the Examiner's conclusion in FF5, Appellants argue that delivery of polynucleotides has multiple uses disclosed in the Specification, such as altering the endogenous properties of cells, blocking gene expression, cleaving cellular RNA, etc. (App. Br. 12). We agree with Appellants that claim 39 sets forth a complete method, and that the skilled artisan would understand the uses of delivering a polynucleotide to a cell.

As to the Examiner's conclusion in FF6, the use of a wherein clause, in and of itself, does not render the claim indefinite.

CONCLUSIONS OF LAW

Thus, we conclude that the meanings of the limitations objected to by the Examiner are clear when read in light of the Specification, and we thus reverse the rejection of claims 1-3, 6-9, 11-14, 16-22, 24-26, 28-31, 34-36, and 39 under 35 U.S.C. § 112, second paragraph.

ISSUE (New Matter)

The Examiner finds that claims 35 U.S.C. § 112, first paragraph, for lack of enablement contain new matter, and thus do not comply with the requirements of 35 U.S.C. § 112, first paragraph.

Appellants contend that "syringe needle" and "impeding blood flow" as used in the claims are supported by the disclosure as filed.

Thus, the issue on Appeal is: Does the disclosure as filed provide written description support for "syringe needle" and "impeding blood flow" as used in the claims?

FINDINGS OF FACT

FF7 The Examiner rejects claims 1-3, 6-9, 11-14, 16-22, 24-26, 28-31, 34-36, and 39 under 35 U.S.C. § 112, first paragraph, as containing subject matter that was not described in the Specification in such a way as to reasonably convey to one skilled in the art, at the time the application was filed, had possession of the claimed invention (Ans. 9).

FF8 The Examiner finds that the term "syringe needle" as used by claims 1 and 39 is not supported by the disclosure as filed (*id.*). The Examiner finds that page 31 of the Specification only provides support for a needle, and pages 23 and 25 only support a catheter (*id.*).

FF9 The Examiner finds further that the phrase "impeding blood flow to the surface of the skin" is also not supported by the disclosure as filed (*id.*). According to the Examiner:

> Pg 3, lines 8-11, and pg 5, lines 5-24, describe "impeding interior blood flow" to the limb by "applying a tourniquet over [sic] the skin." The genus of "impeding blood flow to the surface of the skin" is not the same as "impeding interior blood flow" as expressly taught on pg 3, lines 8-11, or to the limb as implicitly taught on pg 5, lines 7-8, which discusses limb injections and impeding blood flow.

(*Id.* (alteration in original).)

PRINCIPLES OF LAW

The disclosure as originally filed need not provide "*in haec verba* support for the claimed subject matter at issue," rather, the disclosure should convey to one skilled in the art that the inventor had possession of the

invention at the time of filing. *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1323 (Fed. Cir. 2000) (citations omitted).

ANALYSIS

As to the Examiner's finding that "syringe needle" is not supported by the disclosure as filed (FF8), Appellants contend that the term "needle" is found in the Specification In Example 8, and the concept of injecting a fluid into a vessel is supported throughout the Specification (App. Br. 4).

A Specification need not provide *in haec verba* support for a claim term. Thus, we agree with Appellants that reference to a needle along with injecting a fluid into vessel makes "it . . . readily apparent to a person skilled in the art that a needle used to inject a solution into a vessel or a mammal would be a syringe needle." (*Id.*)

As to the Examiner's finding that "impeding blood flow" is not supported by the disclosure as filed (FF9), Appellants argue that the Examiner has read "impeding blood flow" out of context, as the claims require "'applying a device for impeding blood flow to the surface of the skin of said limb.'" (App. Br. 5 (quoting claims 1 and 39).) Appellants note that support for such as device may be found at page 5 of the Specification.

As noted above, the Specification teaches that a cuff may be used to impede blood flow, with an example of such a cuff being a sphygmomanometer (Spec. 5). Thus, the Specification clearly provides support for the limitation "applying a device for impeding blood flow to the surface of the skin of said limb" as required by independent claims 1 and 39.

CONCLUSIONS OF LAW

Thus, we find that the disclosure as filed provides written description support for "syringe needle" and "impeding blood flow" as used in the claims. Thus, the rejection of claims 1-3, 6-9, 11-14, 16-22, 24-26, 28-31, 34-36, and 39 under 35 U.S.C. § 112, first paragraph, as containing new matter, is reversed.

ISSUE (Enablement)

The Examiner concludes that the Specification does not enable the full scope of claims 1-3, 6-9, 11-14, 16-22, 24-26, 28-31, 34-36, and 39.

Appellants contend that the Specification does enable the full scope of the claims.

Thus the issue on Appeal is: Has the Examiner demonstrated that the Specification fails to enable the full scope of claims 1-3, 6-9, 11-14, 16-22, 24-26, 28-31, 34-36, and 39?

FINDINGS OF FACT

FF10 The Examiner rejects claims 1-3, 6-9, 11-14, 16-22, 24-26, 28-31, 34-36, and 39 under 35 U.S.C. § 112, first paragraph, for lack of enablement (Ans. 10).

FF11 According to the Examiner:

> the specification, while being enabling for a method comprising applying a tourniquet to the limb of a mammal such that blood flow of a blood vessel in the limb is occluded and administering naked DNA to said blood vessel distal to the occlusion, wherein said DNA comprises a nucleic acid sequence encoding a protein operably linked to a promoter and wherein said protein is

> expressed to detectable levels in skeletal muscle cells of said limb distal to the occlusion, does not reasonably provide enablement for 1) applying a tourniquet to a limb; inserting an injector into an artery of the limb proximal to the tourniquet, and injecting a polynucleotide through the injector distal to the tourniquet; 2) inserting an injector into an artery of a limb; applying a tourniquet to the limb; and injecting an adenoviral vector through the injector distal to the tourniquet such that the adenoviral vector is delivered to skeletal muscle cells distal to the tourniquet; 3) administering any polynucleotide that does not encode protein operably linked to a promoter, or 4) merely "delivering a polynucleotide" with obtaining expression of the protein encoded by the polynucleotide. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly, connected, to make and/or use the invention commensurate in scope with these claims.

(*Id.*)

FF12 The Examiner concludes that the Specification is not enabled for delivering adenoviral vectors to skeletal muscle cells (*id.* at 11). The Examiner made the following findings with respect to the factors set out in *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).[5]

The breadth of the claims: The Examiner notes that "claims 1 and 39 encompass applying a tourniquet to a leg wherein the tourniquet occludes blood flow between the limb and the rest of the body while at the same time

[5] The factual considerations discussed in *Wands* are: (1) the quantity of experimentation necessary to practice the invention, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

using a perfusion pump that allows blood flow between the limb and the perfusion pump." (Ans. 12.)

FF13 *State of the prior art and level of skill*: The Examiner notes that it was "well known that the conditions required to target a vector to desired tissues of interest in vivo was unpredictable." (*Id.* at 13.)

The Examiner relies on Milas[6], which the Examiner finds demonstrates "that the conditions required to obtain protein expression in skeletal muscles of a limb using a viral vector were unpredictable." (Ans. 13.) Specifically, the Examiner finds that Milas teaches applying a tourniquet to the leg of a rat and using a perfusion pump to deliver adenoviral particles to the femoral artery and vein distal to the tourniquet (*id.*). According to the Examiner, the use of open claim language by claims 1 and 39 allows the claims to read on the method of Milas, whose method did not result in delivery of the adenoviral vector to the skeletal muscle (*id.* at 13-14).

FF14 *The amount of direction or guidance presented and the existence of working examples*: The Examiner finds that the Specification "does not provide any teachings for one of skill to overcome the teachings of Milas or provide any examples of injecting an adenovirus while applying a sphygmomanometer cuff or tourniquet to the skin." (*Id.* at 15.)

FF15 *The quantity of experimentation necessary*: The Examiner concludes that:

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[6] Milas et al., I*solated Limb Perfusion in the Sarcoma-bearing Rat: A Novel Preclinical Gene Delivery System*, 3 CLINICAL CANCER RESEARCH 2197-2203 (1997).

> Given the breadth of the claims taken with the teachings of Milas and the lack of teachings in the specification regarding how to overcome the teachings of Milas and obtain expression in skeletal muscle cells using adenovirus, it would have required one of skill undue experimentation to determine how to perform the steps required to use an adenovirus and obtain expression in skeletal muscle cells as claimed. While non-operative embodiments are allowed in a claim, steps that are not enabled in the specification are not. The claims do not exclude using a perfusion pump while applying a tourniquet. No amount of experimentation would allow one of skill to obtain expression of an adenovirus in skeletal muscle cells by applying a tourniquet while using a perfusion pump as encompassed by the claims.

(*Id.*)

FF16 The Examiner notes further that claims 1 and 39 "encompass applying a tourniquet to a limb; inserting an injection devi[c]e into an artery of the limb either proximally or distally to the tourniquet; and injecting a polynucleotide into the artery distal to the tourniquet." (*Id.* at 11.)

FF17 The Examiner concludes that the Specification "does not teach how to apply a tourniquet to a limb; insert an injection devi[c]e into the limb proximal to the tourniquet; and inject a polynucleotide distal to the tourniquet." (*Id.*)

FF18 The Examiner also concludes that the Specification "does not enable delivering polynucleotides encoding a protein in the absence of a promoter," noting that "the claims should be limited to a polynucleotide encoding a protein operably linked to a promoter." (*Id.* at 16.)

FF19 Finally, the Examiner concludes that for the delivery of a polynucleotide to have an enabled use, it should result in protein expression

at detectable levels, thus "the claims should recite a final step of obtaining detectable levels of expression of the protein." (*Id.*)

PRINCIPLES OF LAW

> When rejecting a claim under the enablement requirement of section 112, the PTO bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by that claim is not adequately enabled by the description of the invention provided in the specification of the application.

In re Wright, 999 F.2d 1557, 1561-62 (Fed. Cir. 1993).

"[T]o be enabling, the specification . . . must teach those skilled in the art how to make and use *the full scope of the claimed invention* without 'undue experimentation.'" *Wright*, 999 F.2d at 1561 (emphasis added), quoted in *Genentech, Inc. v. Novo Nordisk, A/S,* 108 F.3d 1361, 1365 (Fed. Cir. 1997). Thus, "there must be sufficient disclosure, either through illustrative examples or terminology, to teach those of ordinary skill how to make and how to use the invention as broadly as it is claimed." *In re Vaeck*, 947 F.2d 488, 496 & n. 23 (Fed. Cir. 1991), quoted in *Enzo Biochem, Inc. v. Calgene, Inc.,* 188 F.3d 1362, 1374 (Fed. Cir. 1999).

ANALYSIS

As to the Examiner's conclusion that the Specification is not enabled for delivering adenoviral vectors to skeletal muscle cells (FF12-15), the Examiner relies on the Milas reference, which teaches applying a tourniquet to the leg of a rat and using a perfusion pump to deliver adenoviral particles

to the femoral artery and vein distal to the tourniquet (FF13). Thus, the Examiner appears to be requiring that the Specification enable the method of Milas to allow for delivery of polynucleotide to the skeletal muscle of the leg.

Claims 1 and 39 require that external pressure be applied against the skin of a limb of the mammal such that blood flow to and from the limb is impeded. As pointed out by Appellants, Milas notes that requiring brisk outflow of venous blood is important to the method (App. Br. 8, citing Milas, p. 2202, column 1). Appellants argue that in contrast, the present Specification teaches the prevention of outflow (App. Br. 8). Moreover, Appellants assert, the present Specification is drawn to delivery of polynucleotides to skeletal muscle, while Milas is directed to delivering DNA to tumors (*id.*).

We conclude that Appellants have the better position. The Specification specifically provides working Examples where polynucleotides were delivered to skeletal muscle (*see, e.g.,* Spec. 25). In addition, the Specification also teaches that when injections were performed with low intravascular pressure, and thus not impeding blood outflow, "almost no DNA was detected within the muscle tissues or vessels." (*Id.* at 30.) In contrast, the Specification teaches that at high intravascular pressure was used, thus occluding blood outflow, DNA was detected through all of the muscle (*id.*). Thus, one skilled in the art, in view of the teaching of the instant Specification, would understand that Milas may not have obtained delivery of polynucleotide to the skeletal muscle because the method of

Milas requires brisk venous outflow. Thus, the Examiner erred requiring Appellants' Specification to enable the method of Milas.

As to the Examiner's conclusions in FF16 and FF17, Appellants argue that one may insert a catheter in a vessel proximal to the applied pressure, wherein the catheter is pushed to the distal side where the nucleic acids are injected and delivered (App. Br. 6). We agree that the skilled artisan would understand that a catheter could be inserted proximal to the external pressure and then be pushed distal to the applied pressure to deliver the polynucleotide.

As to the Examiner's conclusion in FF18, Appellants argue that "it is known in the art that either the presence or absence of a promoter sequence in the polynucleotide is not likely to have an effect on whether or not the polynucleotide is delivered by the method described in the Specification." (App. Br. 8.) As to the Examiner's conclusions in FF19, Appellants argue further that the "described methods can be used to deliver either polynucleotides that are expressible or polynucleotides that inhibit expression equally well." (*Id.* at 9.)

We agree. The Specification specifically teaches that nucleic acids that block gene expression may also be delivered (*see, e.g.*, Spec. 6), and such polynucleotides would not require a promoter, nor would such nucleotides be expressed. In addition, the Examiner has not provided any scientific reasoning or evidence why such polynucleotides that block expression could not be delivered using the method of delivery taught by the Specification.

CONCLUSIONS OF LAW

We conclude that the Examiner has not demonstrated that the Specification fails to enable the full scope of claims 1-3, 6-9, 11-14, 16-22, 24-26, 28-31, 34-36, and 39, and the rejection of the claims 35 U.S.C. § 112, first paragraph, for lack of enablement, is reversed.

ISSUE (Anticipation)

The Examiner finds that Milas anticipates claims 1, 3, 34, 35, and 39.

Appellants contend the adenovirus of Milas does not deliver polynucleotides to the skeletal muscles of the leg, as Milas teaches that the reporter gene, β-gal, was not detected in the muscular tissue of the perfused leg.

Thus, the issue on Appeal is: Does the fact that Milas detected describes inflammatory infiltrates in the skeletal muscle, without any detectable expression of the marker gene is the muscular tissue, anticipate a method of delivering a polynucleotide to skeletal muscle cells?

FINDINGS OF FACT

FF20 The Examiner rejects claims 1, 3, 34, 35, and 39 under 35 U.S.C. § 102(b) as being anticipated by Milas (Ans. 18).

FF21 The Examiner notes that Milas is interpreted as obtaining delivery of adenovirus to skeletal muscle cells, which is different from the one used in making the enablement rejection, where the reference was interpreted as not obtaining delivery of adenovirus to skeletal muscle cells as expression of the marker gene β-gal was not detected in the muscle cells (*id.* at 11 and 18).

FF22 The Examiner further finds that claims 1 and 39 use open claim language, and thus "encompass occluding blood flow to the limb using a tourniquet while using a perfusion pump that allows blood to flow to the limb." (*Id.* at 19.)

FF23 According to the Examiner, while Milas did not obtain expression of the marker gene, "Milas described the process provided the entire leg with blood . . ., which reasonably implies that adenovirus-laden blood passed from the femoral artery into the muscular branches and was in contact with skeletal muscle cells." (*Id.*)

FF24 The Examiner finds further that Milas describes inflammatory infiltrates in the skeletal muscle, thus implying that a foreign material, the adenovirus, had penetrated the skeletal muscle (*id.*).

PRINCIPLES OF LAW

In order for a prior art reference to serve as an anticipatory reference, it must disclose every limitation of the claimed invention, either explicitly or inherently. *In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997).

ANALYSIS

Appellants argue that the adenovirus of Milas does not deliver polynucleotides to the skeletal muscles of the leg, as Milas teaches that the reporter gene, β-gal, was not detected in the muscular tissue of the perfused leg, with the only difference between the perfused and non-perfused leg being the presence of inflammatory cell infiltrates (App. Br. 13).

Claims 1 and 39 require delivery of a polynucleotide to skeletal

muscle. In the method of Milas, while adenovirus was delivered to tumor/peritumoral tissue as demonstrated by expression of the marker gene, there was no detectable expression of the marker gene in the muscular tissue of the perfused limb (Milas, p. 2201, second column). Thus, even though Milas describes inflammatory infiltrates in the skeletal muscle (FF24), reading the Milas reference as a whole, the fact that the tumor/peritumoral tissue expressed the marker gene, while the skeletal muscle did not, the reference does not support the Examiner's inference that the marker polynucleotide was delivered to the skeletal muscle of the leg (*see, e.g.*, FF13).

CONCLUSIONS OF LAW

We find that the fact that Milas detected describes inflammatory infiltrates in the skeletal muscle, without any detectable expression of the marker gene is the muscular tissue, does not anticipate a method of delivering a polynucleotide to skeletal muscle cells. Thus, we reverse the rejection of claims 1, 3, 34, 35, and 39 under 35 U.S.C. § 102(b) as being anticipated by Milas.

ISSUE (Double Patenting)

The Examiner rejects claims 1-3, 6-9, 11-14, 16-22, 24-26, 28-31, 34-36, and 39 under the judicially created obviousness-type double-patenting as being unpatentable over claims 1-3, 6, 7, 11, 12, 16-20, 24, 25, 28-31, 34-36, and 39-42 over copending application 09/707,117.

Appellants contend that the rejection is obviated because the prior art and the claimed invention are owned or obligated by assignment to the same person.

Thus, the issue on Appeal: Is the fact that the prior art and the claimed invention are owned or obligated by assignment to the same person sufficient to obviate the judicially created obviousness-type double-patenting rejection?

FINDINGS OF FACT

FF25 The Examiner provisionally rejects claims 1-3, 6-9, 11-14, 16-22, 24-26, 28-31, 34-36, and 39 under the judicially created obviousness-type double-patenting as being unpatentable over claims 1-3, 6, 7, 11, 12, 16-20, 24, 25, 28-31, 34-36, and 39-42 over copending application 09/707,117 (Ans. 20).

FF26 The Examiner notes that Appellants stated that they were willing to file a terminal disclaimer as necessary (*id.* at 30).

PRINCIPLES OF LAW

An obviousness-type double patenting rejection may be overcome by the filing of a terminal disclaimer. *See, e.g.*, 37 C.F.R. § 1.321(c).

ANALYSIS

Appellants argue that "the prior art and the claimed invention were, at the time the invention was made, owned by the same person or subject to an

obligation of assignment to the same person. Therefore, the provisional rejection is obviated." (App. Br. 14 (emphasis removed).)

However, the fact that the prior art and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person, is not sufficient to obviate the rejection. Rather, Appellants need to file a terminal disclaimer.

Therefore, as Appellants have not argued the merits of the obviousness-type double patenting rejection, the rejection is affirmed.

CONCLUSIONS OF LAW

The fact that the prior art and the claimed invention are owned or obligated by assignment to the same person is not sufficient to obviate the judicially created obviousness-type double-patenting rejection, and the rejection of claims 1-3, 6-9, 11-14, 16-22, 24-26, 28-31, 34-36, and 39 under the judicially created obviousness-type double-patenting as being unpatentable over claims 1-3, 6, 7, 11, 12, 16-20, 24, 25, 28-31, 34-36, and 39-42 over copending application 09/707,117, is affirmed.

TIME LIMITS

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED

cdc

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